

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TEVA PHARMACEUTICALS)	
INTERNATIONAL GMBH, CEPHALON,)	C.A. No. 23-490-JLH
LLC, and EAGLE PHARMACEUTICALS,)	CONSOLIDATED
INC.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
BENDARX CORP.,)	
)	
Defendant.)	

**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS
OF DEFENDANT BENDARX USA CORP.**

Defendant BendaRx USA Corp. (“BendaRx”) responds to the numbered paragraphs of the Complaint filed by Plaintiffs Teva Pharmaceuticals International GmbH (“Teva Pharmaceuticals”), Cephalon, LLC (“Cephalon”) (collectively, with Teva Pharmaceuticals, “Teva”), and Eagle Pharmaceuticals, Inc. (“Eagle”) (collectively, “Plaintiffs”) as follows:

1. BendaRx admits that these consolidated actions purport to be actions for patent infringement against BendaRx for infringement of U.S. Patent Nos. 8,436,190 (the “190 Patent”), the 8,445,524 (the “524 Patent”), 8,609,863 (the “863 Patent”), 8,669,279 (the “279 Patent”), 8,791,270 (the “270 Patent”), 8,883,836 (the “836 Patent”), 8,895,756 (the “756 Patent”), 9,533,955 (the “955 Patent”), and 8,461,350 (the “350 Patent”) (collectively, the “Patents-in-Suit”), which include patents listed in the U.S. Food and Drug Administration’s (“FDA”) Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) with respect to Treanda® (bendamustine hydrochloride) for Injection, 100 mg/4 mL (25 mg/L) and/or Bendeka® (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL). BendaRx also admits that it submitted a New Drug Application (“NDA”) No. 215291 to the FDA seeking

approval to sell the product that is the subject of its NDA. BendaRx denies the remaining allegations of paragraph 1, and specifically denies any patent infringement as alleged by Plaintiffs.

THE PARTIES

2. BendaRx is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies those allegations.

3. BendaRx is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore denies those allegations.

4. BendaRx is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4, and therefore denies those allegations.

5. BendaRx admits the allegations of paragraph 5.

JURISDICTION

6. BendaRx incorporates its answers to paragraphs 1 through 5 as if set forth fully herein.

7. BendaRx admits that this Court has subject matter jurisdiction over Plaintiffs' claims and that this Court is authorized to grant declaratory judgment relief related to those claims, but denies any patent infringement as alleged by Plaintiffs.

8. BendaRx admits that this Court has personal jurisdiction over BendaRx because BendaRx has consented to this Court's jurisdiction for purposes of these actions only. BendaRx is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 8, and therefore denies those allegations.

9. BendaRx admits that it has consented to this Court's jurisdiction for purposes of these actions only.

10. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10, and therefore denies those allegations.

11. BendaRx admits the allegations of paragraph 11.

VENUE

12. BendaRx incorporates its answers to paragraphs 1 through 11 as if set forth fully herein.

13. BendaRx admits that venue is proper in this District because BendaRx has consented to venue in this District for purposes of these actions only. BendaRx is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13, and therefore denies those allegations.

14. BendaRx admits the allegations of paragraph 14.

15. BendaRx admits the allegations of paragraph 15.

BACKGROUND

16. BendaRx admits the allegations of paragraph 16.

17. BendaRx admits that Bendeka® has been approved by the FDA. BendaRx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17 and therefore denies such allegations.

18. BendaRx admits the allegations of paragraph 18.

19. BendaRx admits that Treanda® has been approved by the FDA. BendaRx lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 and therefore denies such allegations.

20. BendaRx admits that Exhibit A appears to be a copy of the '190 Patent, that the '190 Patent is entitled "Bendamustine Pharmaceutical Compositions," and that it lists an issue date of May 7, 2013. BendaRx admits that the '190 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 and therefore denies such allegations.

21. BendaRx admits that Exhibit B appears to be a copy of the '524 Patent, that the '524 Patent is entitled "Solid Forms of Bendamustine Hydrochloride," and that it lists an issue date of May 21, 2013. BendaRx admits that the '524 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 21 and therefore denies such allegations.

22. BendaRx admits that Exhibit C appears to be a copy of the '863 Patent, that the '863 Patent is entitled "Bendamustine Pharmaceutical Compositions," and that it lists an issue date of December 17, 2013. BendaRx admits that the '863 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 22 and therefore denies such allegations.

23. BendaRx admits that Exhibit D appears to be a copy of the '279 Patent, that the '279 Patent is entitled "Solid Forms of Bendamustine Hydrochloride," and that it lists an issue date of March 11, 2014. BendaRx admits that the '279 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to

form a belief as to the truth of the remaining allegations of paragraph 23 and therefore denies such allegations.

24. BendaRx admits that Exhibit E appears to be a copy of the '270 Patent, and that the '270 Patent is entitled "Bendamustine Pharmaceutical Compositions." BendaRx denies that the issue date is July 27, 2014 as alleged in the Complaint because the '270 Patent lists an issue date of July 29, 2014. BendaRx admits that the '270 patent is listed in connection with Treanda® and Bendeka® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 24 and therefore denies such allegations.

25. BendaRx admits that Exhibit F appears to be a copy of the '836 Patent, that the '836 Patent is entitled "Solid Forms of Bendamustine Hydrochloride," and that it lists an issue date of November 11, 2014. BendaRx admits that the '836 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 25 and therefore denies such allegations.

26. BendaRx admits that Exhibit G appears to be a copy of the '756 Patent, that the '756 Patent is entitled "Bendamustine Pharmaceutical Compositions," and that it lists an issue date of November 25, 2014. BendaRx admits that the '756 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 26 and therefore denies such allegations.

27. BendaRx admits that Exhibit H appears to be a copy of the '955 Patent, that the '955 Patent is entitled "Solid Forms of Bendamustine Hydrochloride," and that it lists an issue

date of January 3, 2017. BendaRx admits that the '955 patent is listed in connection with Treanda® in the Orange Book. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27 and therefore denies such allegations.

28. BendaRx admits that Exhibit I appears to be a copy of the '350 Patent, that the '350 Patent is entitled "Bendamustine Pharmaceutical Compositions," and that it lists an issue date of June 11, 2013. BendaRx otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 28 and therefore denies such allegations.

ALLEGED INFRINGEMENT BY BENDARX

29. BendaRx admits that a First Notice Letter was sent but denies it was from BendaRx Canada. BendaRx admits the remaining allegations of paragraph 29.

30. BendaRx admits Plaintiffs sued BendaRx Canada in the District of Delaware, but otherwise denies the allegations of paragraph 30, and specifically denies any patent infringement as alleged by Plaintiffs.

31. BendaRx admits the allegations of paragraph 31.

32. BendaRx admits the allegations of paragraph 32.

33. BendaRx admits the allegations of paragraph 33.

34. BendaRx admits that it attached a Detailed Statement to its First and Second Notice Letters, but denies the remaining allegations of paragraph 34.

35. BendaRx denies the allegations of paragraph 35.

36. BendaRx denies the allegations of paragraph 36.

37. BendaRx admits that BendaRx's NDA Product does not contain mannitol or tertiary-butyl alcohol ("TBA"), but denies the remaining allegations of paragraph 37.

38. BendaRx denies the allegations of paragraph 38.

39. BendaRx admits that BendaRx's NDA Product does not produce an X-ray powder diffraction pattern comprising the following reflections: 8.3, 16.8, and 18.5 ± 0.2 degrees 2θ , but denies the remaining allegations of paragraph 39.

40. BendaRx denies the allegations of paragraph 40.

41. BendaRx admits that BendaRx's NDA Product does not contain mannitol or TBA, but denies the remaining allegations of paragraph 41.

42. BendaRx denies the allegations of paragraph 42.

43. BendaRx admits that BendaRx's NDA Product does not produce an X-ray powder diffraction pattern comprising the following reflections: 7.9, 15.5, and 26.1 ± 0.2 degrees 2θ , but denies the remaining allegations of paragraph 43.

44. BendaRx denies the allegations of paragraph 44.

45. BendaRx denies the allegations of paragraph 45.

46. BendaRx admits that BendaRx's NDA Product does not contain bendamustine hydrochloride, but denies the remaining allegations of paragraph 46.

47. BendaRx denies the allegations of paragraph 47.

48. BendaRx admits that BendaRx's NDA Product does not produce an X-ray powder diffraction pattern comprising the following reflections: 7.9 and 15.5, and 26.1 ± 0.2 degrees 2θ , but denies the remaining allegations of paragraph 48.

49. BendaRx denies the allegations of paragraph 49.

50. BendaRx admits that BendaRx's NDA Product does not contain mannitol, but denies the remaining allegations of paragraph 50.

51. BendaRx denies the allegations of paragraph 51.

52. BendaRx admits that BendaRx's NDA Product does not produce an X-ray powder diffraction pattern having peaks at 7.9 and 15.5 ± 0.2 degrees 2θ , but denies the remaining allegations of paragraph 52.

53. BendaRx denies the allegations of paragraph 53.

54. BendaRx admits that BendaRx's First Notice Letter included a document entitled "Offer of Confidential Access," but denies the remaining allegations of paragraph 54.

55. BendaRx admits that BendaRx's Second Notice Letter included a document entitled "Offer of Confidential Access," but denies the remaining allegations of paragraph 55.

56. BendaRx admits Plaintiffs sued BendaRx Canada in the District of Delaware, but otherwise denies the allegations of paragraph 56, and specifically denies any patent infringement as alleged by Plaintiffs.

57. BendaRx admits the allegations of paragraph 57.

58. BendaRx admits the allegations of paragraph 58.

59. BendaRx admits that Plaintiffs "maintained their position that BendaRx Canada is a proper defendant in these actions," but denies that BendaRx Canada is a proper defendant in said actions.

60. BendaRx admits the allegations of paragraph 60.

61. BendaRx admits the allegations of paragraph 61.

62. BendaRx admits the Amended Complaint was filed, but denies the remaining allegations of paragraph 62, and specifically denies any patent infringement as alleged by Plaintiffs.

**COUNT I: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,436,190 UNDER 35 U.S.C. SECTION 271(E)(2)**

63. BendaRx incorporates its answers to paragraphs 1 through 62 as if set forth fully herein.

64. The allegations of paragraph 64 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 64 and specifically denies that the BendaRx NDA Product infringes the '190 Patent.

65. BendaRx denies the allegations of paragraph 65.

66. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

67. BendaRx denies the allegations of paragraph 67.

68. BendaRx denies the allegations of paragraph 68.

69. BendaRx denies the allegations of paragraph 69.

70. BendaRx denies the allegations of paragraph 70.

71. BendaRx denies the allegations of paragraph 71.

72. BendaRx denies the allegations of paragraph 72.

**COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,436,190**

73. BendaRx incorporates its answers to paragraphs 1 through 72 as if set forth fully herein.

74. BendaRx admits the allegations of paragraph 74.

75. BendaRx denies the allegations of paragraph 75.

76. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

77. BendaRx denies the allegations of paragraph 77.

78. BendaRx denies the allegations of paragraph 78.

79. BendaRx denies the allegations of paragraph 79.

80. BendaRx denies the allegations of paragraph 80.

81. BendaRx denies the allegations of paragraph 81.

82. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '190 Patent, but denies the remaining allegations of paragraph 82.

83. BendaRx denies the allegations of paragraph 83.

84. BendaRx denies the allegations of paragraph 84.

**COUNT III: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,445,524 UNDER 35 U.S.C. SECTION 271(E)(2)**

85. BendaRx incorporates its answers to paragraphs 1 through 84 as if set forth fully herein.

86. The allegations of paragraph 86 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 86 and specifically denies that the BendaRx NDA Product infringes the '524 Patent.

87. BendaRx denies the allegations of paragraph 87.

88. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

89. BendaRx denies the allegations of paragraph 89.

90. BendaRx denies the allegations of paragraph 90.

91. BendaRx denies the allegations of paragraph 91.

92. BendaRx denies the allegations of paragraph 92.

93. BendaRx denies the allegations of paragraph 93.

94. BendaRx denies the allegations of paragraph 94.

**COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,445,524**

95. BendaRx incorporates its answers to paragraphs 1 through 94 as if set forth fully herein.

96. BendaRx admits the allegations of paragraph 96.

97. BendaRx denies the allegations of paragraph 97.

98. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

99. BendaRx denies the allegations of paragraph 99.

100. BendaRx denies the allegations of paragraph 100.

101. BendaRx denies the allegations of paragraph 101.

102. BendaRx denies the allegations of paragraph 102.

103. BendaRx denies the allegations of paragraph 103.

104. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '524 Patent, but denies the remaining allegations of paragraph 104.

105. BendaRx denies the allegations of paragraph 105.

106. BendaRx denies the allegations of paragraph 106.

**COUNT V: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,609,863 UNDER 35 U.S.C. SECTION 271(E)(2)**

107. BendaRx incorporates its answers to paragraphs 1 through 106 as if set forth fully herein.

108. The allegations of paragraph 108 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 108 and specifically denies that the BendaRx NDA Product infringes the '863 Patent.

109. BendaRx denies the allegations of paragraph 109.

110. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

111. BendaRx denies the allegations of paragraph 111.

112. BendaRx denies the allegations of paragraph 112.

113. BendaRx denies the allegations of paragraph 113.

114. BendaRx denies the allegations of paragraph 114.

115. BendaRx denies the allegations of paragraph 115.

116. BendaRx denies the allegations of paragraph 116.

**COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,609,863**

117. BendaRx incorporates its answers to paragraphs 1 through 116 as if set forth fully herein.

118. BendaRx admits the allegations of paragraph 118.

119. BendaRx denies the allegations of paragraph 119.

120. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

121. BendaRx denies the allegations of paragraph 121.

122. BendaRx denies the allegations of paragraph 122.

123. BendaRx denies the allegations of paragraph 123.

124. BendaRx denies the allegations of paragraph 124.

125. BendaRx denies the allegations of paragraph 125.

126. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '863 Patent, but denies the remaining allegations of paragraph 126.

127. BendaRx denies the allegations of paragraph 127.

128. BendaRx denies the allegations of paragraph 128.

**COUNT VII: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,669,279 UNDER 35 U.S.C. SECTION 271(E)(2)**

129. BendaRx incorporates its answers to paragraphs 1 through 128 as if set forth fully herein.

130. The allegations of paragraph 130 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 130 and specifically denies that the BendaRx NDA Product infringes the '279 Patent.

131. BendaRx denies the allegations of paragraph 131.

132. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

133. BendaRx denies the allegations of paragraph 133.

134. BendaRx denies the allegations of paragraph 134.

135. BendaRx denies the allegations of paragraph 135.

136. BendaRx denies the allegations of paragraph 136.

137. BendaRx denies the allegations of paragraph 137.

138. BendaRx denies the allegations of paragraph 138.

**COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,669,279**

139. BendaRx incorporates its answers to paragraphs 1 through 138 as if set forth fully herein.

140. BendaRx admits the allegations of paragraph 140.

141. BendaRx denies the allegations of paragraph 141.

142. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

143. BendaRx denies the allegations of paragraph 143.

144. BendaRx denies the allegations of paragraph 144.

145. BendaRx denies the allegations of paragraph 145.

146. BendaRx denies the allegations of paragraph 146.

147. BendaRx denies the allegations of paragraph 147.

148. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '279 Patent, but denies the remaining allegations of paragraph 148.

149. BendaRx denies the allegations of paragraph 149.

150. BendaRx denies the allegations of paragraph 150.

**COUNT IX: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,791,270 UNDER 35 U.S.C. SECTION 271(E)(2)**

151. BendaRx incorporates its answers to paragraphs 1 through 150 as if set forth fully herein.

152. The allegations of paragraph 152 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 152 and specifically denies that the BendaRx NDA Product infringes the '270 Patent.

153. BendaRx denies the allegations of paragraph 153.

154. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

155. BendaRx denies the allegations of paragraph 155.

156. BendaRx denies the allegations of paragraph 156.

157. BendaRx denies the allegations of paragraph 157.

158. BendaRx denies the allegations of paragraph 158.

159. BendaRx denies the allegations of paragraph 159.

160. BendaRx denies the allegations of paragraph 160.

**COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,791,270**

161. BendaRx incorporates its answers to paragraphs 1 through 160 as if set forth fully herein.

162. BendaRx admits the allegations of paragraph 162.

163. BendaRx denies the allegations of paragraph 163.

164. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

165. BendaRx denies the allegations of paragraph 165.

166. BendaRx denies the allegations of paragraph 166.

167. BendaRx denies the allegations of paragraph 167.

168. BendaRx denies the allegations of paragraph 168.

169. BendaRx denies the allegations of paragraph 169.

170. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '270 Patent, but denies the remaining allegations of paragraph 170.

171. BendaRx denies the allegations of paragraph 171.

172. BendaRx denies the allegations of paragraph 172.

**COUNT XI: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,883,836 UNDER 35 U.S.C. SECTION 271(E)(2)**

173. BendaRx incorporates its answers to paragraphs 1 through 172 as if set forth fully herein.

174. The allegations of paragraph 174 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 174 and specifically denies that the BendaRx NDA Product infringes the '836 Patent.

175. BendaRx denies the allegations of paragraph 175.

176. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

177. BendaRx denies the allegations of paragraph 177.

178. BendaRx denies the allegations of paragraph 178.

179. BendaRx denies the allegations of paragraph 179.

180. BendaRx denies the allegations of paragraph 180.

181. BendaRx denies the allegations of paragraph 181.

182. BendaRx denies the allegations of paragraph 182.

**COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,883,836**

183. BendaRx incorporates its answers to paragraphs 1 through 182 as if set forth fully herein.

184. BendaRx admits the allegations of paragraph 184.

185. BendaRx denies the allegations of paragraph 185.

186. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

187. BendaRx denies the allegations of paragraph 187.

188. BendaRx denies the allegations of paragraph 188.

189. BendaRx denies the allegations of paragraph 189.

190. BendaRx denies the allegations of paragraph 190.

191. BendaRx denies the allegations of paragraph 191.

192. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '836 Patent, but denies the remaining allegations of paragraph 192.

193. BendaRx denies the allegations of paragraph 193.

194. BendaRx denies the allegations of paragraph 194.

**COUNT XIII: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,895,756 UNDER 35 U.S.C. SECTION 271(E)(2)**

195. BendaRx incorporates its answers to paragraphs 1 through 194 as if set forth fully herein.

196. The allegations of paragraph 196 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 196 and specifically denies that the BendaRx NDA Product infringes the '756 Patent.

197. BendaRx denies the allegations of paragraph 197.

198. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

199. BendaRx denies the allegations of paragraph 199.

200. BendaRx denies the allegations of paragraph 200.

201. BendaRx denies the allegations of paragraph 201.

202. BendaRx denies the allegations of paragraph 202.

203. BendaRx denies the allegations of paragraph 203.

204. BendaRx denies the allegations of paragraph 204.

**COUNT XIV: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,895,756**

205. BendaRx incorporates its answers to paragraphs 1 through 204 as if set forth fully herein.

206. BendaRx admits the allegations of paragraph 206.

207. BendaRx denies the allegations of paragraph 207.

208. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

209. BendaRx denies the allegations of paragraph 209.

210. BendaRx denies the allegations of paragraph 210.

211. BendaRx denies the allegations of paragraph 211.

212. BendaRx denies the allegations of paragraph 212.

213. BendaRx denies the allegations of paragraph 213.

214. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '756 Patent, but denies the remaining allegations of paragraph 214.

215. BendaRx denies the allegations of paragraph 215.

216. BendaRx denies the allegations of paragraph 216.

**COUNT XV: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 9,533,955 UNDER 35 U.S.C. SECTION 271(E)(2)**

217. BendaRx incorporates its answers to paragraphs 1 through 216 as if set forth fully herein.

218. The allegations of paragraph 218 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 218 and specifically denies that the BendaRx NDA Product infringes the '955 Patent.

219. BendaRx denies the allegations of paragraph 219.

220. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

221. BendaRx denies the allegations of paragraph 221.

222. BendaRx denies the allegations of paragraph 222.

223. BendaRx denies the allegations of paragraph 223.

224. BendaRx denies the allegations of paragraph 224.

225. BendaRx denies the allegations of paragraph 225.

226. BendaRx denies the allegations of paragraph 226.

**COUNT XVI: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 9,533,955**

227. BendaRx incorporates its answers to paragraphs 1 through 226 as if set forth fully herein.

228. BendaRx admits the allegations of paragraph 228.

229. BendaRx denies the allegations of paragraph 229.

230. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA, in accordance with the label approved by the FDA.

231. BendaRx denies the allegations of paragraph 231.

232. BendaRx denies the allegations of paragraph 232.

233. BendaRx denies the allegations of paragraph 233.

234. BendaRx denies the allegations of paragraph 234.

235. BendaRx denies the allegations of paragraph 235.

236. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '955 Patent, but denies the remaining allegations of paragraph 236.

237. BendaRx denies the allegations of paragraph 237.

238. BendaRx denies the allegations of paragraph 238.

**COUNT XVII: ALLEGED INFRINGEMENT BY BENDARX
OF U.S. PATENT NO. 8,461,350 UNDER 35 U.S.C. SECTION 271(E)(2)**

239. BendaRx incorporates its answers to paragraphs 1 through 238 as if set forth fully herein.

240. The allegations of paragraph 240 relating to 35 U.S.C. § 271(e)(2)(A) state a legal conclusion to which no response is required. BendaRx denies the remaining allegations of paragraph 240 and specifically denies that the BendaRx NDA Product infringes the '350 Patent.

241. BendaRx denies the allegations of paragraph 241.

242. BendaRx admits that it will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

243. BendaRx denies the allegations of paragraph 243.

244. BendaRx denies the allegations of paragraph 244.

245. BendaRx denies the allegations of paragraph 245.

246. BendaRx denies the allegations of paragraph 246.

247. BendaRx denies the allegations of paragraph 247.

248. BendaRx denies the allegations of paragraph 248.

**COUNT XVIII: DECLARATORY JUDGMENT OF INFRINGEMENT
BY BENDARX OF U.S. PATENT NO. 8,461,350**

249. BendaRx incorporates its answers to paragraphs 1 through 248 as if set forth fully herein.

250. BendaRx admits the allegations of paragraph 250.

251. BendaRx denies the allegations of paragraph 251.

252. BendaRx admits that it will engage in commercial manufacture, use and sale of the BendaRx's NDA Product upon FDA approval of BendaRx's NDA in accordance with the label approved by the FDA.

253. BendaRx denies the allegations of paragraph 253.

254. BendaRx denies the allegations of paragraph 254.

255. BendaRx denies the allegations of paragraph 255.

256. BendaRx denies the allegations of paragraph 256.

257. BendaRx denies the allegations of paragraph 257.

258. BendaRx admits that there is a justiciable controversy between Plaintiffs and BendaRx regarding infringement of the '350 Patent, but denies the remaining allegations of paragraph 258.

259. BendaRx denies the allegations of paragraph 259.

260. BendaRx denies the allegations of paragraph 260.

AFFIRMATIVE DEFENSES

As its separate affirmative defenses to Plaintiffs' claims and allegations, BendaRx alleges as follows:

FIRST AFFIRMATIVE DEFENSE

BendaRx has not infringed and does not infringe any valid and enforceable claim of the Patents-in-Suit.

SECOND AFFIRMATIVE DEFENSE

One or more of the claims of the Patents-in-Suit are invalid for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrine of unclean hands.

FOURTH AFFIRMATIVE DEFENSE

This action or any relief sought by Plaintiff is barred, in whole or in part, by additional affirmative defenses that cannot now be asserted due to the generality of Plaintiff's pleadings and the fact that discovery has not been completed.

COUNTERCLAIMS

BendaRx USA Corp. ("BendaRx") by and through its undersigned attorneys, brings the following Counterclaims against Teva Pharmaceuticals International GmbH ("Teva Pharmaceuticals"), Cephalon, LLC ("Cephalon") (collectively, with Teva Pharmaceuticals, "Teva"), and Eagle Pharmaceuticals, Inc. ("Eagle") (collectively, "Plaintiffs" or "Counterclaim-Defendants") and alleges as follows.

NATURE OF THE ACTION

1. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* In bringing this action, BendaRx seeks a declaration of non-infringement and/or invalidity of U.S. Patent Nos. 8,436,190

(the “190 Patent”), the 8,445,524 (the “524 Patent”), 8,609,863 (the “863 Patent”), 8,669,279 (the “279 Patent”), 8,791,270 (the “270 Patent”), 8,883,836 (the “836 Patent”), 8,895,756 (the “756 Patent”), 9,533,955 (the “955 Patent”), and 8,461,350 (the “350 Patent”) (collectively, the “Patents-in-Suit”) and a declaration that BendaRx is free to continue to seek approval for its New Drug Application (“NDA”) No. 215291, and upon approval by the U.S. Food and Drug administration (“FDA”) to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in NDA No. 215291.

THE PARTIES

2. Defendant/Counterclaim-Plaintiff BendaRx is a corporation organized and existing under the laws of Virginia, having a registered agent at 4445 Corporation Lane, Suite 264, Virginia Beach 23462.

3. Plaintiff/Counterclaim-Defendant Teva Pharmaceuticals purports to be a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

4. Plaintiff/Counterclaim-Defendant Cephalon purports to be a limited liability company organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

5. Plaintiff/Counterclaim-Defendant Eagle purports to be a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

6. BendaRx incorporates each of the proceeding paragraphs 1-5 as if fully set forth herein.

7. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing BendaRx in this District and because, on information and belief, Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular contact with, this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

A. Bendeka

10. Eagle purports to hold NDA No. 208194 for Bendeka® (bendamustine hydrochloride) for injection, 100 mg/4 mL (25 mg/mL).

B. Treanda

11. Cephalon purports to hold NDA Nos. 22249 and 22303 for Treanda® (bendamustine hydrochloride) for injection, 100 mg/4 mL (25 mg/mL).

C. Patents-in-Suit

12. The '270 Patent is listed in the electronic version of the FDA's publication *Approved Drug Products and Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 208194 for Bendeka®.

13. On information and belief, Plaintiffs/Counterclaim-Defendants caused FDA to publish the Patents-in-Suit in the Orange Book in connection with NDA No. 208194.

14. The '190, '524, '863, '279, '270, '836, '756, and '955 Patents are listed in the Orange Book in connection with NDA Nos. 22249 and 22303 for Treanda®.

15. On information and belief, Plaintiffs/Counterclaim-Defendants caused FDA to publish the Patents-in-Suit in the Orange Book in connection with NDA Nos. 22249 and 22303.

16. On February 23, 2024, Plaintiffs filed an Amended Complaint in this Court seeking, among other things, a judgment that BendaRx infringed the '190, '524, '863, '279, '270, '836, '756, '955, and '350 Patents by submitting NDA No. 215291, and that making, using, selling, offering to sell, or importing the product described in NDA No. 215291 ("BendaRx's NDA Product"), or inducing or contributing to such conduct, would constitute infringement of the '190, '524, '863, '279, '270, '836, '756, '955, and '350 Patents. As such, an immediate and justiciable controversy exists between BendaRx, on the one hand, and Plaintiffs, on the other, regarding whether BendaRx's NDA Product infringes any valid and enforceable claim of the '190, '524, '863, '279, '270, '836, '756, '955, and '350 Patents.

D. BendaRx's NDA No. 215291

17. BendaRx submitted NDA No. 215291 to FDA, seeking approval to engage in the commercial manufacture, use, or sale of BendaRx's NDA Product.

18. BendaRx's NDA No. 215291 includes certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to, *inter alia*, the '190, '524, '863, '279, '270, '836, '756, and '955 Patents, stating that, in BendaRx's opinion and to the best of its knowledge, such patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of BendaRx's NDA Product.

19. In accordance with the requirements of 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52(c), BendaRx sent Plaintiffs notice letters dated March 23, 2023 and May 5, 2023

(“Notice Letters”), stating that BendaRx’s NDA No. 215291 included Paragraph IV Certifications, alleging that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of BendaRx’s NDA Product.

20. BendaRx’s Notice Letters included an Offer for Confidential Access (“OCA”) to NDA No. 215291 for the holders of NDA Nos. 208194, 22249, and 22303, and owners of the Patents-in-Suit so that they could determine whether BendaRx’s NDA Product infringes any valid and enforceable claim of the Patents-in-Suit, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

21. Pursuant to § 505(j)(2)(B)(iv)(II) of the Federal Food Drug and Cosmetic Act, BendaRx attached to their Notice Letters a detailed statement of the factual and legal bases for BendaRx’s Paragraph IV Certifications (“Detailed Statement”).

22. BendaRx’s Notice Letters initiated a 45-day statutory period during which Plaintiffs had the opportunity to file an action for patent infringement.

23. On May 4, 2023, Plaintiffs sued BendaRx in this District for alleged infringement of the ’190 Patent, ’524 Patent, ’863 Patent, ’279 Patent, ’270 Patent, ’836 Patent, ’756 Patent, ’955 Patent, 9,572,887 (“the ’887 Patent”), 8,076,366 (“the ’366 Patent”), and the ’350 Patent (Case No. 1:23-cv-00490-JLH). On June 9, 2023, Plaintiff filed a second suit against BendaRx alleging infringement of the same patents (Case No. 1:23-cv-00633-JLH). On January 19, 2024, the parties stipulated to the dismissal of the ’887 and ’366 Patents, which the court entered on January 25, 2024. The two actions were consolidated on February 9, 2024. BendaRx denies all allegations of infringement.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’190 Patent)

24. BendaRx incorporates each of the proceeding paragraphs 1-23 as if fully set forth herein.

25. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '190 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '190 Patent.

26. Because Plaintiffs maintain and BendaRx denies that the '190 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '190 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

27. The claims of the '190 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the '190 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

28. BendaRx is entitled to a declaration that the claims of the '190 Patent are invalid.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '190 Patent)

29. BendaRx incorporates each of the proceeding paragraphs 1-28 as if fully set forth herein.

30. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '190 Patent.

31. BendaRx seeks a declaration that no valid or enforceable claim of the '190 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

32. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '190 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

33. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '190 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '190 patent.

34. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '190 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '524 Patent)

35. BendaRx incorporates each of the proceeding paragraphs 1-34 as if fully set forth herein.

36. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '524 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '524 Patent.

37. Because Plaintiffs maintain and BendaRx denies that the '524 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '524 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

38. The claims of the '524 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in

combination with other prior art. Additionally, the claims of the '524 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

39. BendaRx is entitled to a declaration that the claims of the '524 Patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '524 Patent)

40. BendaRx incorporates each of the proceeding paragraphs 1-39 as if fully set forth herein.

41. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '524 Patent.

42. BendaRx seeks a declaration that no valid or enforceable claim of the '524 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

43. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '524 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

44. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '524 patent, a declaration of rights between the parties is appropriate and necessary to establish

that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '524 patent.

45. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '524 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '863 Patent)

46. BendaRx incorporates each of the proceeding paragraphs 1-45 as if fully set forth herein.

47. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '863 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '863 Patent.

48. Because Plaintiffs maintain and BendaRx denies that the '863 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '863 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

49. The claims of the '863 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L.

Teagarden & D.S. Baker, “Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems,” 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., “Stabilität von Bendamustinhydrochlorid in Infusionslösungen,” 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the ’863 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

50. BendaRx is entitled to a declaration that the claims of the ’863 Patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the ’863 Patent)

51. BendaRx incorporates each of the proceeding paragraphs 1-51 as if fully set forth herein.

52. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the ’863 Patent.

53. BendaRx seeks a declaration that no valid or enforceable claim of the ’863 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx’s NDA No. 215291.

54. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx’s Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the ’863 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

55. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '863 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '863 patent.

56. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '863 patent.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '279 Patent)

57. BendaRx incorporates each of the proceeding paragraphs 1-56 as if fully set forth herein.

58. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '279 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '279 Patent.

59. Because Plaintiffs maintain and BendaRx denies that the '279 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '279 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including

§§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

60. The claims of the '279 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the '279 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

61. BendaRx is entitled to a declaration that the claims of the '279 Patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '279 Patent)

62. BendaRx incorporates each of the proceeding paragraphs 1-61 as if fully set forth herein.

63. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '279 Patent.

64. BendaRx seeks a declaration that no valid or enforceable claim of the '279 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

65. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for

why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '279 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

66. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '279 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '279 patent.

67. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '279 patent.

NINTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '270 Patent)

68. BendaRx incorporates each of the proceeding paragraphs 1-67 as if fully set forth herein.

69. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '270 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '270 Patent.

70. Because Plaintiffs maintain and BendaRx denies that the '270 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '270 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

71. In accordance with 21 U.S.C. § 355(j)(2)(B), through its Notice Letter, which is incorporated herein by reference, BendaRx has provided Plaintiffs with a detailed statement of the factual and legal bases for why the claims of the '270 Patent are invalid. BendaRx reserves the right to assert additional grounds of invalidity.

72. BendaRx is entitled to a declaration that the claims of the '270 Patent are invalid.

TENTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '270 Patent)

73. BendaRx incorporates each of the proceeding paragraphs 1-73 as if fully set forth herein.

74. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '270 Patent.

75. BendaRx seeks a declaration that no valid or enforceable claim of the '270 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

76. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for

why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '270 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

77. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '270 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '270 patent.

78. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '270 patent.

ELEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '836 Patent)

79. BendaRx incorporates each of the proceeding paragraphs 1-78 as if fully set forth herein.

80. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '836 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '836 Patent.

81. Because Plaintiffs maintain and BendaRx denies that the '836 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '836 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

82. The claims of the '836 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the '836 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

83. BendaRx is entitled to a declaration that the claims of the '836 Patent are invalid.

TWELFTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '836 Patent)

84. BendaRx incorporates each of the proceeding paragraphs 1-83 as if fully set forth herein.

85. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '836 Patent.

86. BendaRx seeks a declaration that no valid or enforceable claim of the '836 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

87. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '836 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

88. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '836 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '836 patent.

89. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '836 patent.

THIRTEENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '756 Patent)

90. BendaRx incorporates each of the proceeding paragraphs 1-90 as if fully set forth herein.

91. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a

declaration that the claims of the '756 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '756 Patent.

92. Because Plaintiffs maintain and BendaRx denies that the '756 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '756 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

93. The claims of the '756 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the '756 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

94. BendaRx is entitled to a declaration that the claims of the '756 Patent are invalid.

FOURTEENTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '756 Patent)

95. BendaRx incorporates each of the proceeding paragraphs 1-94 as if fully set forth herein.

96. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '756 Patent.

97. BendaRx seeks a declaration that no valid or enforceable claim of the '756 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

98. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '756 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

99. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '756 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '756 patent.

100. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '756 patent.

FIFTEENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '955 Patent)

101. BendaRx incorporates each of the proceeding paragraphs 1-100 as if fully set forth herein.

102. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '955 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '955 Patent.

103. Because Plaintiffs maintain and BendaRx denies that the '955 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '955 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

104. The claims of the '955 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in combination with other prior art. Additionally, the claims of the '955 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

105. BendaRx is entitled to a declaration that the claims of the '955 Patent are invalid.

SIXTEENTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '955 Patent)

106. BendaRx incorporates each of the proceeding paragraphs 1-105 as if fully set forth herein.

107. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '955 Patent.

108. BendaRx seeks a declaration that no valid or enforceable claim of the '955 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

109. In accordance with 21 U.S.C. § 355(j)(2)(B), BendaRx's Detailed Statement, which is incorporated herein by reference, included a detailed statement of the factual and legal bases for why BendaRx has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, the doctrine of patent exhaustion, or the doctrine of implied license, of the '955 patent. BendaRx reserves the right to assert additional grounds of non-infringement.

110. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '955 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '955 patent.

111. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '955 patent.

SEVENTEENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '350 Patent)

112. BendaRx incorporates each of the proceeding paragraphs 1-111 as if fully set forth herein.

113. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '350 Patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and BendaRx concerning the invalidity of the claims of the '350 Patent.

114. Because Plaintiffs maintain and BendaRx denies that the '350 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '350 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116, and/or the doctrine of obviousness-type double-patenting, and/or any other judicially created requirements for patentability and enforceability of patents.

115. The claims of the '350 Patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 by at least the Ribomustin® Product Monograph, D.L. Teagarden & D.S. Baker, "Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems," 15 Eur. J. Pharm. Sci. 115 (2002), and Maas et al., "Stabilität von Bendamustinhydrochlorid in Infusionslösungen," 49 Pharmazie 775 (1994), either alone or in

combination with other prior art. Additionally, the claims of the '350 Patent are invalid under 35 U.S.C. § 112 as indefinite and for lack of written description and/or enablement. BendaRx reserves the right to assert additional grounds of invalidity.

116. BendaRx is entitled to a declaration that the claims of the '350 Patent are invalid.

EIGHTEENTH COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '350 Patent)

117. BendaRx incorporates each of the proceeding paragraphs 1-116 as if fully set forth herein.

118. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.* There is an actual, substantial, and continuing case or controversy between BendaRx and Plaintiffs regarding, *inter alia*, the noninfringement of the '350 Patent.

119. BendaRx seeks a declaration that no valid or enforceable claim of the '350 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of the product described in BendaRx's NDA No. 215291.

120. Plaintiffs allege in the Amended Complaint that BendaRx infringes the '350 Patent.

121. BendaRx has not infringed and is not now infringing, either literally or under the doctrine of equivalents, any valid, enforceable claim of the '350 Patent.

122. BendaRx has not made, used, sold, offered for sale, or imported into the United States, and is not making, using, selling, offering for sale, or importing into the United States, any product that infringes any claim of the '350 Patent, either literally or under the doctrine of equivalents.

123. BendaRx's manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 does not actively induce others to infringe claims of the '350 Patent.

124. Because Plaintiffs maintain that the commercial manufacture, use, offer for sale, or sale of the product described in NDA No. 215291 would directly and/or indirectly infringe the '350 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the product described in BendaRx's NDA No. 215291 within the United States have not infringed and will not infringe, directly and/or indirectly, the '350 patent.

125. BendaRx is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of the product described in NDA No. 215291 has not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '350 patent.

PRAYER FOR RELIEF

WHEREFORE, BendaRx requests that this Court enter judgment:

- (a) that Plaintiffs take nothing against BendaRx by its Complaint in this action;
- (b) finding, declaring, and adjudging in favor of BendaRx and against Plaintiffs, dismissing with prejudice all claims of Plaintiffs against BendaRx;
- (c) finding declaring, and adjudging that every claim of the Patents-in-Suit is invalid;
- (d) finding, declaring, and adjudging that BendaRx does not infringe any valid and enforceable claim of the Patents-in-Suit, directly or indirectly, either literally or under the doctrine of equivalents, nor has it ever done so;
- (e) finding this to be an exceptional case under 35 U.S.C. § 285, and awarding to BendaRx its costs (including expert witness fees), disbursements, and reasonable attorney's fees) incurred in this action and such other relief as may be appropriate; and
- (f) granting such other and further relief as this Court may deem just and proper.

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